

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	10/623,039-Conf. #1401			
Filing Date	July 18, 2003			
First Named Inventor	Subhashis BANERJEE			
Art Unit	1643			
Examiner Name	D. J. Blanchard			
Attorney Docket Number	BBI-8188			

			U.S. PA	TENT DOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ² (<i>if known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A1*	US-5,231,024	07-27-1993	Moeller et al.	
	A2*	US-5,654,407	08-05-1997	Boyle et al.	
	A3*	US-5,705,389	01-06-1998		
	A4*	US-5,795,967	08-18-1998	Aggarwal et al.	
	A5*	US-5,859,205	01-12-1999	Adair et al.	
	A6*	US-5,877,293	03-02-1999	Adair et al.	
	A7*	US-5,929,212	07-27-1999	Jolliffe et al.	
	A8*	US-5,994,510	11-30-1999	Adair et al.	
	A9*	US-6,214,870	04-10-2001	McClure et al.	
		US-6,235,281	05-22-2001	Stenzel et al.	
	A11*	US-6,258,562	07-10-2001	Salfeld et al.	
	A12*	US-6,270,766	08-07-2001	Feldman et al.	-
	A13*	US-20030092059-A1	05-15-2003	Salfeld et al.	
	A14*	US-20030235585-A1	12-25-2003	Fischkoff et al.	-
	A15*	US-20040033228-A1	02-19-2004	Krause et al.	
	A16*	US-20040126372-A1	07-01-2004	Banerjee et al.	
	A17*	US-20040131614-A1	07-08-2004	Banerjee et al.	
	A18*	US-20040136989-A1	07-15-2004	Banerjee et al.	
	A19*	US-20040136990-A1	07-15-2004	Banerjee et al.	
	A20*	US-20040151722-A1	08-05-2004	Banerjee et al.	
	A21*	US-20040166111-A1	08-26-2004	Kaymakcalan et al.	
****	A22*	US-20040219142-A1	11-04-2004	Banerjee et al.	
	A23*	US-20060009385-A1	01-12-2006	Hoffman et al.	
	A24*	US-20060153846-A1	07-13-2006	Krause et al.	

		FOREI	GN PATENT	DOCUMENTS	 -	
Examiner Initials*	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	7⁵
	B1	EP-0101681-B1	03-07-1984	The Rockefeller University		
	B2	EP-0186833-B1	07-09-1986	Yeda Research and Development Company Limited		
	В3	EP-0212489-B1	03-04-1987	The Rockefeller University		
	B4	EP-0351789-B1	01-24-1990	Chiron Corporation		
	B5	EP-0366043-B1	05-02-1990	Otsuka Pharmaceutical Co., Ltd.		
	В6	WO-91/02078-A1	02-21-1991	Peptide Technology, Ltd.		
	B7	WO-91/09967-A1	07-11-1991	Celltech Limited		
	В8	EP-0492448-B1	07-01-1992	Pharmacia & Upjohn S.p.A.		
	В9	WO-92/11383-A1	07-09-1992	Celltech Limited		
	B10	WO-92/16553-A1	10-01-1992	New York University et al.		
	B11	WO-93/06213-A1	04-01-1993	Medical Research Council et al.		

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B12	WO-93/11793-A1	06-24-1993	Schering Corporation	\neg
B13	EP-0614984-B1	09-14-1994	Bayer Corporation	
B14	GB-2279077	12-21-1994	Celltech Limited	
B15	WO-94/29347-A1	12-22-1994	Therapeutic Antibodies, Inc.	
B16	EP-0659766-A1	06-28-1995	Schering-Plough	\neg
B17	WO-95/23813-A1	09-08-1995	Merck & Co., Inc.	
B18	WO-97/29131-A1	08-14-1997	BASF Aktiengesellschaft	
B19	WO-98/05357-A1	02-12-1998	The Kennedy Institute of Rheumatology	
B20	WO-01/00229-A1	01-04-2001	Pharmacia Corporation	\neg
B21	WO-02/100330-A3	12-19-2002	Abbott Biotechnology Ltd.	
B22	WO-06/041970-A2	04-20-2006	Abbott Biotechnology Ltd.	
B23	WO-04/092448-A2	10-28-2004	Newmont USA Limited	

Examiner	Date
Signature	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁴ Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	C1	Abraham, Edward, et al., "Efficacy and Safety of Monoclonal Antibody to Human Tumor Necrosis Factor α in Patients with Sepsis Syndrome," <i>JAMA</i> , Vol. 273(12):934-941 (1995)	
	C2	Awni, Walid M. et al., "Steady-State Pharmacokinetics (PK) of Adalimumab (HUMIRA™, Abbott) Following 40 mg Subcutaneous (sc) Injection Every Other Week (eow) in Rheumatoid Arthritis (RA) Patients with and without Methotrexate (MTX) Background Therapy," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S140 (2003)	
	C3	Bansback, Nick J. et al., "The Cost Effectiveness of Adalimumab (HUMIRA™, Abbott) in the Treatment of Patients with Moderate to Severe Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 48 (Suppl. 9):S611 (2003)	
	C4	BARBUTO, J.A.M. et al. "Production of Neutralizing Antibodies to Tumor Necrosis Factor by Human Tumor-Infiltrating B Lymphocytes" <i>Proc. Am. Assoc. Cancer Res.</i> , 34:487, Abstr. 2904 (1993)	
	C5	Barrera, P. et al., "Drug survival, efficacy and toxicity of monotherapy with a fully human anti-tumour necrosis with a fully human anti-tumour necrosis factor-α antibody compared with methotrexate in long-standing rheumatoid arthritis," <i>Rheumatology</i> , Vol. 41:430-439 (2002)	
	C6	Barrera, Pilar et al., "Effect of a Fully Human Anti-TNF α Monoclonal Antibody on the Local and Systemic Expression of TNF α and IL-1 β ," <i>Arthritis Rheum.</i> , Vol. 42(9 Suppl.):S75 (1999)	
	C7	BENDTZEN, K. et al. "Auto-antibodies to IL-1a and TNFa in Normal Individuals and in Infectious and Immunoinflammatory Disorders" The Physiological and Pathological Effects of Cytokines, 447-52 (1990)	
	C8	Boekstegers, P., et al., "Repeated administration of a F(ab')2 fragment of an anti-tumor	

Substitute for form 1449/PTO				Complete if Known		
				Application Number	10/623,039-Conf. #1401	
IN	IFORMATION	l DI	SCLOSURE	Filing Date	July 18, 2003	
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(Use as many sheets as necessary)				Examiner Name	D. J. Blanchard	
Sheet	3	of	10	Attorney Docket Number	BBI-8188	

 		
	recrosis factor alpha monoclonal antibody in patients with severe sepsis: effects on the cardiovascular system and cytokine levels," <i>Shock</i> , Vol. 1(4):237-245 (1994)	
C9	Bombardier, C. et al., "Pattern of DMARD use in a North American Cohort of Patients with Early Rheumatoid Arthritis (RA) (SONORA)," Arthritis Rheum., Vol. 46(9 Suppl.):S344 (2002)	
C10	BOYLE, P. et al. "A Novel Monoclonal Human IgM Autoantibody which Binds Recombinant Human and Mouse Tumor Necrosis Factor- a" Cell. Immunol., 152:556-68 (1993)	
C11	BOYLE, P. et al. "The B5 Monoclonal Human Autoantibody Binds to Cell Surface TNFa on Human Lymphoid Cells and Cell Lines and Appears to Recognize a Novel Epitope" Cell. Immunol., 152:569-81 (1993)	
C12	Breedveld, F.C. et al., "Sustained Efficacy Over 4 Years with Adalimumab in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):169 (2003)	
C13	Breedveld, Ferdinand C. et al., "Sustained Efficacy over 5 Years with Adalimumab (HUMIRA™) in Patients with Active Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S118 (2003)	
C14	Breedveld, F. et al., "The Long-term Efficacy and Safety of Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in the Treatment of Rheumatoid Arthritis: Results of a 2-Year Study," <i>JCR: Journal of Clinical Rheumatology,</i> Vol. 8(Suppl. 3):S46 (2002)	
C15	Breedveld, F.C. et al., "The Fully Human Anti-TNF Antibody Adalimumab (D2E7) in Combination with Methotrexate (MTX) in the Treatment of Active Rheumatoid Arthritis: Results of a 2-Year Study," Presented at: The Annual Meeting of the European League Against Rheumatism (EULAR), Prague, Czech Republic, June 2001	
C16	Brekke, Ole Henrik et al., "Therapeutic Antibodies for Human Diseases at the Dawn of the Twenty-first Century," <i>Nature</i> , Vol. 2:52-62 (2002)	
C17	Burmester, G.R. et al., "Long-Term Efficiacy and Safety of Adalimumab (D2E7) Monotherapy in Patients With DMARD-Refractory Rheumatoid Arthritis - Results From a 2-Year Study," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S537 (2002)	
C18	Burmester, G.R. et al., "Effect of Dose Interruptions on the Efficacy and Safety of Adalimumab in Patients with RA," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):192 (2003)	
C19	Burmester, G.R. et al., "Sustained Efficacy of Adalimumab Monotherapy for More than Four Years in DMARD-Refractory RA," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):192-3 (2003)	
C20	Case, John P., "Old and New Drugs Used in Rheumatoid Arthritis: A Historical Perspective," American Journal of Therapeutics, Vol. 8:163-179 (2001)	
C21	Chartash, E.K. et al., "Adalimumab Improves Fatigue in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):349 (2003)	
C22	CHOW, A.W. et al. "Effect of monoclonal antibody on human tumor necrosis factor (TNF MAb) on TNF α , IL-1 β , and IL-6 levels in patients with sepsis syndrome" Clinical Research, 42:2 299A (1994)	
C23	Cohen, Jonathan, et al., "Intersept: An international, multicenter, placebo-controlled trial of monoclonal anitbody to human tumor necrosis factor-α in patients with sepsis," <i>Crit Care Med,</i> Vol. 24(9):1431-1440 (1996)	
C24	COX, J.P.L. et al. "A directory of human germ-line V _x segments reveals a strong bias in their usage" <i>Eur. J. Immunol.</i> , 24(2):827-36 (1994)	
C25	den Broeder, A.A. et al, "The Effect of D2E7, a new human anti-TNFα monoclonal antibody, on the oxidative burst of PMN in patients with RA," <i>Arthritis and Rheumatism</i> , Vol. 41(9):S57	
C26	den Broeder, Alfons et al., "A Single Dose, Placebo Controlled Study of the Fully Human Anti- Tumor Necrosis Factor-α Antibody Adalimumab (D2E7) in Patients with Rheumatoid Arthritis," <i>The Journal of Rheumatology</i> , Vol. 29(11):2288-2298 (2002)	
C27	den Broeder, A.A. et al., "Long term anti-tumour necrosis factor α monotherapy in rheumatoid	

Complete if Known Substitute for form 1449/PTO **Application Number** 10/623,039-Conf. #1401 **INFORMATION DISCLOSURE** July 18, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Subhashis BANERJEE Art Unit 1643 (Use as many sheets as necessary) D. J. Blanchard Examiner Name Sheet 4 of 10 Attorney Docket Number BBI-8188

	T	
	arthritis: effect on radiological course and prognostic value of markers of cartilage turnover and endothelial activation," <i>Ann. Rheum. Dis.</i> , Vol. 61:311-318 (2002)	
C28	Department of Surgery, Univeristy of Toronto, Annual Report (1998-1999)	
C29	Egan, L.J. et al, "A randomized, single-blind, pharmacokinetic and doseresponse study of subcutaneous methotrexate, 15 and 25 MG/week, for refractory ulcerative colitis and Crohn's Disease," <i>Gastroenterology</i> , Vol. 114(4):G3978 (1998)	
C30	ELLIOTT, M.J. et al. "Treatment of rheumatoid arthritis with chimeric monoclonal antibodies to tumor necrosis factor a" Arthritis & Rheumatism, 36(12):1681-90 (1993)	
C31	Emery, Paul et al., "Changes in PRO-MMP-1 in Relation to Standard Measures of Disease Activity Over a 6 Month Treatment Period with Adalimumab (D2E7) in Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 44(9):S215 (2001)	
C32	Emery, Paul et al., "Improvement in HAQ Disability in Rheumatoid Arthritis (RA) with Adalimumab (HUMIRA™) Based on Duration of Disease," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S313 (2003)	
C33	Feldmann, Marc et al., "Anti-TNFα Therapy of Rheumatoid Arthritis: What Have We Learned," <i>Annu. Rev. Immunol.</i> , Vol. 19:163-196 (2001)	
C34	Figini, Mariangela et al., "In Vitro Assembly of Repertoires of Antibody Chains on the Surface of Phage by Renaturation," <i>J. Mol. Biol.</i> , Vol. 239:68-78 (1994)	
C35	FOMSGAARD, A. <i>et al.</i> "Auto-antibodies to Tumour Necrosis Factor <i>α</i> in Healthy Humans and Patients with Inflammatory Diseases and Gram-Negative Bacterial Infections" <i>Scand. J. Immunol.</i> , 30:219-23 (1989)	
C36	Furst, D.E. et al., "Safety and Efficacy of Adalimumab (D2E7), a Fully Human Anti-TNF-α Monoclonal Antibody, Given in Combination with Standard Antirheumatic Therapy: Safety Trial of Adalimumab in Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S572 (2002)	
C37	Furst, Daniel E. et al., "Adalimumab, a Fully Human Anti-Tumor Necrosis Factor-α Monoclonal Antibody, and Concomitant Standard Antirheumatic Therapy for the Treatment of Rheumatoid Arthritis: Results of STAR (Safety Trial of Adalimumab in Rheumatoid Arthritis)," <i>The Journal of Rheumatology,</i> Vol. 30(12):2563-2571 (2003)	
C38	Furst, Daniel et al., "TNF Blockade by the Fully Human Monoclonal Antibody Adalimumab (D2E7), in the Armada Trial Resuts in Decreases in Serum Matrix Metalloproteinase (MMP) Levels Along with Impressive Clinical Improvement in Refractory RA Patients," <i>Arthritis Rheum.</i> , Vol. 44(9 Suppl.):S215 (2001)	
C39	Furst, Daniel E. et al., "Improvement of the Individual ACR Components in ACR20 Responders in an Adalimumab (HUMIRA™) RA Clinical Trial," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S106 (2003)	
C40	Goto, Daisuke et al., "Adalimumab," Medline AC NLM12510366 (2002)	
C41	Goto, Daisuke et al., "Adalimumab," Nippon Rinsho, 60(12): 2384-2389 (2002)	
C42	Granneman, Richard G. et al., "Pharmacokinetic/Pharmacodynamic (PK/PD) Relationships of Adalimumab (HUMIRA™, Abbott) in Rheumatoid Arthritis (RA) Patients during Phase II/III Clinical Trials," <i>Arthritis. Rheum.</i> , Vol. 48(Suppl. 9):S140 (2003)	
C43	GRIFFITHS, A.D. et al. "Human anti-self antibodies with high specificity from phage display libraries" <i>The EMBO J.</i> , 12(2):725-34 (1993)	
C44	Hawkins, Robert E. et al., "Selection of Phage Antibodies by Binding Affinity Mimicking Affinity Maturation," <i>J. Mol. Biol.</i> , Vol. 226:889-896 (1992)	
C45	Holler, E. et al., "Modulation of Acute Graft-Versus-Host Disease After Allogeneic Bone Marrow Transplantation by Tumor Necrosis Factor α (TNFα) Release in the Course of Pretransplant Conditioning: Role of Conditioning Regimens and Prophylactic Application of a Monoclonal Antibody Neutralizing Human TNFα (MAK 195F)," <i>Blood</i> , Vol. 86(3):890-899 (1995)	

Substitute for form 1449/PTO				Complete if Known		
				Application Number	10/623,039-Conf. #1401	
IN	IFORMATIC	ON DIS	SCLOSURE	Filing Date	July 18, 2003	
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	(Use as many	sheets as	necessary)	Examiner Name	D. J. Blanchard	
Sheet	5	of	10	Attorney Docket Number	BBI-8188	

C46	Holliger, Philipp et al., "Engineered antibody fragments and the rise of single domains," <i>Nature Biotechnology</i> , Vol. 23(9):1126-1136 (2005)	
C47	Hoogenboom, Hennie R. et al., "Converting rodent into human antibodies by guided selection," Antibody Engineering, Oxford University Press, Chpt. 8, pgs. 169-185 (1996)	
C48	HUSE, W.D. et al. "Generation of a large combinatorial library of the immunoglobulin repertoire in phage lambda" <i>Science</i> , 246:1275-81 (1989)	
C49	Janeway, Charles A., Jr., "The structure of a typical antibody molecule," <i>Immunobiology</i> , Vol. 5, Garland Publishing (2001)	
C50	Janeway, Charles A., Jr., "The Protein Products of MHC class I and class II genes are highly polymorphic," Immunobiolgy, Third Edition, pgs. 4:24-4:30 (1997)	
C51	Jespers, Laurent S. et al., "Guiding the Selection of Human Antibodies from Phage Display Repertoires to a Single Epitope of an Antigen," <i>Bio/Technology</i> , Vol. 12:899-903 (1994)	
C52	Kanakoudi-Tsakalidou, F. et al., "Influenza vaccination in children with chronic rheumatic diseases and long-term immunosuppressive therapy," <i>Clinical and Experimental Rheumatology</i> , Vol. 19:589-594 (2001)	
C53	Kavanaugh, A.F. et al., "The Armada Trial: 12-Month Efficacy and Safety of Combination Therapy with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, and Methotrexate (MTX) in Patients with Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.,</i> Vol. 61(Suppl. I):S168 (2002)	
C54	Kavanaugh, A. et al., "Immune Response is Not Affected by Adalimumab Therapy," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):169 (2003)	
C55	Kavanaugh, Arthur F. et al., "Treatment with Adalimumab (D2E7) does not Affect Normal Immune Responsiveness," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S132 (2002)	
C56	Kaymakcalan, Z. et al., "Comparison of Adalimumab (D2E7), Infliximab, and Etanercept in the Prevention of Polyarthritis in the Transgene Murine Model of Rheumatoid Arthritis," <i>Arthritis, Rheum.</i> , Vol. 46(9 Suppl.):S304 (2002)	
C57	Kaymakcalan, Z. et al., "Murine Model for Assessing Adalimumab, Inflixmab, and Etanercept to Prevent Polyarthritis," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):136-7 (2003)	
C58	Kempeni, Joachim, "Update on D2E7: a fully human anti-tumour necrosis factor α monoclonal antibody," <i>Ann. Rheum. Dis.</i> , Vol. 59(Suppl. 1):144-145 (2000)	
C59	Kempeni, Joachim, "Preliminary Results of early clinical trials with the fully human anti-TNFα monoclonal antibody D2E7," <i>Ann. Rheum. Dis.</i> , Vol. 58(Suppl. 1):170-172 (1999)	
C60	Keystone, Edward et al., "The Armada Trial: A Double-Blind Placebo Controlled Trial of the Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), in Patients with Active RA on Methotrexate (MTX)," <i>Arthritis & Rheumatism</i> , Vol. 44(9):S213 (2001)	
C61	Keystone, E. et al., "Response to Adalimumab in Patients with Early Versus Late Rheumatoid Arthritis (RA)," Ann. Rheum. Dis., Vol. 62(Suppl. 1):170 (2003)	
C62	Keystone, E. et al., "Adalimumab Inhibits the Progression of Structural Joint Damage in Patients with Active RA," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):64-5 (2003)	
C63	Keystone, Edward et al., "Sustained Radiographic Inhibition with Adalimumab (HUMIRA TM) over 2 years in Patients with Long Standing Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S315 (2003)	
C64	Keystone, E. et al., "The Fully Human Anti-TNF Monoclonal Antibody, Adalimumab (D2E7), Dose Ranging Study: The 24-Week Clinical Results in Patients with Active RA on Methotrexate Therapy (The ARMADA Trial)," Presented at the Annual Meeting of the European League Against Rheumatoid Arthritis (EULAR), Prague, Czech Republic, (2001)	
C65	Keystone, E.C. et al., "Subgroup Analysis of Radiographic Progression in RA Patients with Moderate Disease Treated with Adalimumab (HUMIRA®)," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):169 (2003)	

Substitu	ute for form 1449/PTO)		Complete if Known		
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Sheet	6	of	10	Attorney Docket Number	BBI-8188	

 C66 Keystone, E. et al., "Efficacy and Safety of Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in MTX Partial Responders: Results of the 24-Week ARMADA Trial," JCR: Journal of Clinical Rheumatology, Vol. 9(Suppl. 3):S69 (2002) C67 Kremer, Joel M., "Rational Use of New and Existing Disease-Modifying Agents in Rheumatoid Arthritis," Ann. Interm. Med., Vol. 134:695-706 (2001) C68 LERNER, R.A. et al. "Antibodies without immunization" Science, 258:1313-14 (1992) C69 LEUSCH, H-G. et al. "Failure to demonstrate TNFα-specific autoantibodies in human sera by ELISA and Western blot" J. Immunol. Methods, 139:145-47 (1991) C70 LEWIS et al. "Use of alanine scanning mutagenesis to improve the affinity of an anti gp120 (HIV) antibody." J. Cell. Biochem., 18D:215 (1994) C71 Low, Nigel M., thesis extract, Cambridge University (1996) C72 Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," J. Mol. Biol., vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," Expert Opin. Biol. Ther., vol. 3(2):351-360 (2003) C74 MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" J. Mol. Biol. 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," Ann. Rheum. Dis., vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MCLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor α: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al. "Combination Therapy wi
Arthritis," Ann. Intern. Med., Vol. 134:695-706 (2001) C68 LERNER, R. et al. "Antibodies without immunization" Science, 258:1313-14 (1992) C69 LEUSCH, H-G. et al. "Failure to demonstrate TNFα-specific autoantibodies in human sera by ELISA and Western blot" J. Immunol. Methods, 139:145-47 (1991) C70 LEWIS et al. "Use of alanine scanning mutagenesis to improve the affinity of an anti gp120 (HIV) antibody." J. Cell. Biochem., 18D:215 (1994) C71 Low, Nigel M., thesis extract, Cambridge University (1996) C72 Low, Nigel M., thesis extract, Cambridge University (1996) C73 Machold, Klaus P. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," J. Mol. Biol., Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," Expert Opin. Biol. Ther., Vol. 3(2):351-360 (2003) C74 MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" J. Mol. Biol. 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," Ann. Rheum. Dis., Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor σ: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al., "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumation Atthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (20
 C68 LERNER, R. A. et al. "Antibodies without immunization" Science, 258:1313-14 (1992) C69 LEUSCH, H-G. et al. "Failure to demonstrate TNFα-specific autoantibodies in human sera by ELISA and Western blot" J. Immunol. Methods, 139:145-47 (1991) C70 LEWIS et al. "Use of alanine scanning mutagenesis to improve the affinity of an anti gp120 (HIV) antibody." J. Cell. Biochem., 18D:215 (1994) C71 Low, Nigel M., thesis extract, Cambridge University (1996) C72 Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," J. Mol. Biol., Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," Expert Opin. Biol. Ther., Vol. 3(2):351-360 (2003) C74 MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" J. Mol. Biol. 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," Ann. Rheum. Dis., Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor a: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfa
ELISA and Western blot" <i>J. Immunol. Methods</i> , 139:145-47 (1991) C70 LEWIS <i>et al.</i> "Use of alanine scanning mutagenesis to improve the affinity of an anti gp120 (HIV) antibody." <i>J. Cell. Biochem.</i> , 18D:215 (1994) C71 Low, Nigel M., thesis extract, Cambridge University (1996) C72 Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i> , Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-a antibody for treatment of inflammatory joint disease," <i>Expert Opin. Biol. Ther.</i> , Vol. 3(2):351-360 (2003) C74 MARKS, J.D. <i>et al.</i> "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" <i>J. Mol. Biol.</i> 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," <i>Bio/Technology</i> , Vol. 12:1134-1136 (1994) C77 MÖLLER, A. <i>et al.</i> "Monoclonal antibodies to human tumor necrosis factor <i>a</i> : in vitro and vivo application" <i>Cytokine</i> , 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i> , Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," <i>Ann. Intern. Med.</i> , Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i> , Vol. 25:83-88 (2000) C82 Rau, R. et al., "Expert Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," <i>Ann. </i>
 (HIV) antibody." <i>J. Cell. Biochem.</i>, 18D:215 (1994) C71 Low, Nigel M., thesis extract, Cambridge University (1996) C72 Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i>, Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," <i>Expert Opin. Biol. Ther.</i>, Vol. 3(2):351-360 (2003) C74 MARKS, J.D. <i>et al.</i> "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" <i>J. Mol. Biol.</i> 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," <i>Ann. Rheum. Dis.</i>, Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," <i>Bio/Technology</i>, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. <i>et al.</i> "Monoclonal antibodies to human tumor necrosis factor α: in vitro and vivo application" <i>Cytokine</i>, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i>, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al., "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," <i>Ann. Intern. Med.</i>, Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i>, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i>, Vol. 25:83-88 (2000) C82 Rau, R. et al., "Erfahrungen mit D2E7," <i>S55</i> (2002) C83 Rau, R. et al., "Kombinationstherape mit dem humanen Anti-TNF-Antikörper D2E7 und
 C72 Low, Nigel M. et al., "Mimicking Somatic Hypermutation: Affinity Maturation of Antibodies Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i>, Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," <i>Expert Opin. Biol. Ther.</i>, Vol. 3(2):351-360 (2003) C74 MARKS, J.D. <i>et al.</i> "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" <i>J. Mol. Biol.</i> 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," <i>Ann. Rheum. Dis.</i>, Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," <i>Bio/Technology</i>, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. <i>et al.</i> "Monoclonal antibodies to human tumor necrosis factor α: in vitro and vivo application" <i>Cytokine</i>, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i>, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," <i>Ann. Intern. Med.</i>, Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i>, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i>, Vol. 25:83-88 (2000) C82 Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i>, Vol. 25:83-88 (2000) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
Displayed on Bacteriophage Using a Bacterial Mutator Strain," <i>J. Mol. Biol.</i> , Vol. 260:359-368 (1996) C73 Machold, Klaus P. et al., "Adalimumab - a new TNF-α antibody for treatment of inflammatory joint disease," <i>Expert Opin. Biol. Ther.</i> , Vol. 3(2):351-360 (2003) C74 MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" <i>J. Mol. Biol.</i> 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," <i>Bio/Technology</i> , Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor <i>a</i> : in vitro and vivo application" <i>Cytokine</i> , 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," <i>Current Opinion in Structural Biology</i> , Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," <i>Ann. Intern. Med.</i> , Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," <i>Akt. Rheumatol.</i> , Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S55 (2002)
joint disease," Expert Opin. Biol. Ther., Vol. 3(2):351-360 (2003) C74 MARKS, J.D. et al. "By-passing immunization: Human antibodies from V-gene libraries displayed on phage" J. Mol. Biol. 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor a: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intem. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
displayed on phage" J. Mol. Biol. 222:581-97 (1991) C75 Massarotti, E.M. et al., "Treatment Patterns in Early-onset Rheumatoid Arthritis (RA): Results from the Sonora Study," Ann. Rheum. Dis., Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor a: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002)
from the Sonora Study," Ann. Rheum. Dis., Vol. 61(Suppl. I):S93 (2002) C76 Medynski, Dan, "Phage Display: All Dressed UP and Ready to Role," Bio/Technology, Vol. 12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor a: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
12:1134-1136 (1994) C77 MÖLLER, A. et al. "Monoclonal antibodies to human tumor necrosis factor a: in vitro and vivo application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
application" Cytokine, 2(3):162-69 (1990) C78 Nilsson, Björn, "Antibody engineering," Current Opinion in Structural Biology, Vol. 5:450-456 (1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
(1995) C79 Pincus, Theodore et al, "Combination Therapy with Multiple Disease-Modifying Antirheumatic Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
Drugs in Rheumatoid Arthritis: A Preventive Strategy," Ann. Intern. Med., Vol. 131:768-774 (1999) C80 Rau, Rolf et al., "Long-term efficiacy and tolerability of multiple I.V. doses of the fully human Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
Anti-TNF-Antibody D2E7 in patients with Rheumatoid Arthritis," Arthritis & Rheumatism, Vol. 41(Suppl.):S55, No. 137 (1998) C81 Rau, R. et al., "Erfahrungen mit D2E7," Akt. Rheumatol., Vol. 25:83-88 (2000) C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
C82 Rau, R. et al., "2.5-Year Treatment Results with Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
Anti-TNF Monoclonal Antibody, in Combination with Methotrexate in Active Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 61(Suppl. 1):S55 (2002) C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und
C83 Rau, R. et al., "Kombinationstheraipe mit dem humanen Anti-TNF-Antikörper D2E7 und Methotrexat bei aktiver chronischer Polyarthritis " Z. Rheumatol. Vol. 58(Suppl. 1):1/35 E20
(1999)
C84 Rau, R., " Erfahrungen mit D2E7," Z. Rheumatol., Vol. 58(Suppl. 1):1/21, S51 (1999)
C85 Rau, R. et al., "Wirkung under Verträglichkeit wiederholter intravenöser Gaben der humanen anti-TNF Antikörpers D2E7 bei Patienten mit chronischer Polyarthritis," Z. Rheumatol., Vol. 58(Suppl. 1):1/41, P12 (1999)
C86 Rau, R. et al., "Treatment with Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, Slows Radiographic Disease Progression in Rheumatoid Arthritis: Results of a 12-Month Study," J. Clin. Rheum., Vol. 8(Suppl.):S78 (2002)
C87 Rau, R.et al., "Adalimumab Inhibits Radiographic Disease Progression in Long-Standing, Rapidly Progressive Rheumatoid Arthritis," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):191 (2003)

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	(Use as many sh	eets as	necessary)	Examiner Name	D. J. Blanchard	
Sheet	7	of	10	Attorney Docket Number	BBI-8188	

	C88	Rau, R., "Adalimumab (a fully human anti-tumour necrosis factor α monoclonal antibody) in the treatment of active rheumatoid arthritis: the initial results of five trials," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. II):ii70-ii73 (2002)	
	C89	Rau, R. et al., "Long-term Treatment with the Fully Human Anti-TNF-Antybody D2E7 Slows Radio-graphic Disease Progression in Rheumatoid Arthritis," <i>Arthritis and Rheumatism</i> , Vol. 42(9):S400 (1999)	
	C90	Reinhart, Konrad et al., "Assessment of the safety and efficacy of the monoclonal anti-tumor necrosis factor antibody-fragment, MAK 195F, in patients with sepsis and septic shock: A multicenter, randomized, placebo-controlled, dose-ranging study," <i>Crit. Care. Med.</i> , Vol. 24(5):733-742 (1996)	
,	C91	Revicki, D. et al., "Treatment with Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Improves Physical Function, Vitality, and Mental Health While Reducing Bodily Pain in Patients with Active Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S537 (2002)	
	C92	Riechmann, Lutz et al., "Phage Display and Selection of a Site-Directed Randomized Single-Chain Antibody Fv Fragment for Its Affinity Improvement," <i>Biochemistry</i> , Vol. 32:8848-8855 (1993)	
	C93	Salfeld, J. et al., "Generation of Fully Human Anti-TNF Antibody D2E7," Arthritis Rheum., Vol. 41(9 Suppl.):S57 (1998)	
	C94	Santora, L.C. et al., "Characterization of Noncovalent Complexes of Recombinant Human Monoclonal Antibody and Antigen Using Carbon Exchange, Size Exclusion Chromatography, and BlAcore," <i>Analytical Biochemistry</i> , Vol. 299(2):119-129 (2001)	
	C95	Santora, L.C. et al., "Characterization of Recombinant Human Monoclonal Tissue Necrosis Factor-α Antibody Using Cation-Exchange HPLC and Capillary Isoelectric Focusing," Analytical Biochemistry, Vol. 275:98-108 (1999)	
	C96	Schattenkirchner, M. et al., "Long-term Use of the Fully Human Anti-TNF Antibody D2E7 in Combination with Methotrexate in Active Rheumatoid Arthritis," <i>Presented at: The Annual Meeting of the European League Against Rheumatism</i> , pg. S228 (2001)	
	C97	Schattenkirchner, M. et al., "Long-term Use of the Fully Human Anti-TNF Antibody Adalimumab (D2E7) in Dmard-refractory Rheumatoid Arthritis," Presented at: The Annual Meeting of the European League Against Rheumatism (EULAR), Prague, Czech Republic, June 2001	
	C98	Schattenkirchner, M. et al., "Phase-1-Studie zur Wirksamkeit und Verträglichkeit Wöchentlicher subcutaner Injekttionen des humanen Anti-TNF-Antikörpers D2E7 bei cP," Z. Rheumatol., Vol. 58(Suppl. 1):1/42, P14 (1999)	√
	C99	Schattenkirchner, M. et al, "Efficacy and Tolerability of Weekly Subcutaneous Injections of the Fully Human Anti-TNF-Antibody D2E7 in Patients with Rheumatoid Arthritis - Results of a Phase I Study," <i>Arthritis and Rheumatism</i> , Vol. 41(9):S57 (1998)	
	C100	Schiff, M. et al., "Rates of Infection in Adalimumab Rheumatoid Arthritis Clinical Trials," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):184 (2003)	
	C101	Schiff, M. et al., "A Randomized, Controlled, Safety Trial of Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Given to RA Patients in Combination with Standard Rheumatologic Care: The STAR (Safety Trial of Adalimumab in Rheumatoid Arthritis) Trial," Ann. Rheum .Dis., Vol. 61(Suppl. 1):S169 (2002)	
	C102	Schiff, M. et al., "Efficacy of Adalimumab Measured by the Disease Activity Score 28 (DAS28) and EULAR Response Criteria," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):170 (2003)	
	C103	Schiff, Michael A. et al., "Malignancies in Rheumatoid Arthritis (RA) Clinical Trials with Adalimumab (HUMIRA™)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S700 (2003)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Art Unit	1643			
Examiner Name	D. J. Blanchard			
Attorney Docket Number	BBI-8188			

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	C104	Schiff, Michael H. et al., "Sustained Efficacy of Adalimumab (HUMIRA™) Plus Methotrexate in Rheumatoid Arthritis (RA) Patients," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S314 (2003)	
	C105	Sibilia, Jean, "Combinaison de traitements de fond dans la polyarthrite rhumatoïde," <i>Ann. Med. Interne.</i> , Vol. 153(1):41-52 (2002)	
	C106	Siegel, Jeffrey N. et al., "Evidence of Effects of a TNF Blocking Agent in ACR20 Non-Responders," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S127 (2003)	
-	C107	Smolen, Josef S. et al., "Objectives and Strategies for Rheumatoid Arthritis Therapy: Yesterday vs. Today," <i>Drugs of Today</i> , Vol. 39(Suppl. B):3-8 (2003)	
	C108	Smolen, J.S. et al., "A Comparison of the SDAI and DAS28 as Measures of Response in Adalimumab (HUMIRA™) Clinical Trials in Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S107 (2003)	
	C109	Strand, V. et al., "Treatment with Adalimumab (D2E7), a Fully Human Anti-TNF Monoclonal Antibody, Improves Physical Function and Health Related Quality of Life (HRQOL) in Patients with Active Rheumatoid Arthritis (RA)," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. I):S175 (2002)	
	C110	Strand, Vibeke et al., "Improvement in Health-related Quality of Life, Health Utility, and Fatigue in Patients with Active Rheumatoid Arthritis (RA) on Adalimumab (HUMIRA™, Abbott) Therapy," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S402 (2003)	
	C111	Strand, V. et al., "Adalimumab Improves Health-related Quality of Life in Rheumatoid Arthritis Patients," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):356 (2003)	
	C112	Thomas, Clayton L., Taber's Cyclopedic Medical Dictionary, F.A. Davis Company, pgs. 118-119 (1977)	
	C113	Thompson, Julia et al., "Affinity Maturation of a High-affinity Human Monoclonal Antibody Against the Third Hypervariable Loop of Human Immunodeficiency Virus: Use of Phage Display to Improve Affinity and Broaden Strain Reactivity," <i>J. Mol. Biol.</i> , Vol. 256:77-88 (1996)	
	C114	Tomlinson, Ian M. et al., "The Repertoire of Human Germline V _H Sequences Reveals about Fifty Groups of V _H Segments with Different Hypervariable Loops," <i>J. Mol. Biol.</i> , Vol. 227:776-798 (1992)	
	C115	Tomlinson, lan M. et al., "The structural repertoire of the human V_{κ} domain," <i>The EMBO Journal</i> , Vol. 14(18):4628-4638 (1995)	
	C116	Tracey, Kevin J. et al., "Tumor Necrosis Factor: A Pleiotropic Cytokine and Therapeutic Target," <i>Annu. Rev. Med.</i> , Vol. 45:491-503 (1994)	
	C117	Tugwell, P. et al., "Adalimumab Improves Utility and Quality-adjusted Life Days in Rheumatoid Arthritis," Ann. Rheum. Dis., Vol. 62(Suppl. 1):107-8 (2003)	
	C118	Tugwell, P. et al., "Relationship Between ACR Response and HRQL in Adalimumab Clinical Trials," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):536 (2003	
	C119	Vajdos, Felix F. et al., "Comprehensive Functional Maps of the Antigen-binding Site of an Anti- ErbB2 Antibody Obtained with Shotgun Scanning Mutagenesis," <i>J. Mol. Biol.</i> , Vol. 320:415- 428 (2002)	
	C120	van de Putte, L.B.A. et al., "One Year Efficacy Results of the Fully Human Anti-TNF Antibody D2E7 in Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 43(9 Suppl.):S269 (2000)	
	C121	Van De Putte, L.B. et al., "Adalimumab (D2E7), the Fully Human Anti-TNF Monoclonal Antibody, in the Treatment of Patients with Rheumatoid Arthritis Who Failed Previous DMARD Therapy: Efficacy and Safety Results from a 6-Month Phase III Study," <i>JCR: Journal of Clinical Rheumatology,</i> Vol. 8(Suppl. 3):S89 (2002)	
	C122	Van de Putte, Atkins Malaise et al., "Adalimumab (D2E7) Monotherapy in the Treatment of Patients with Severely Active Rheumatoid Arthritis (RA)," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S171 (2002)	

Substit	ute for form 1449/PTO			Complete if Known	
				Application Number	10/623,039-Conf. #1401
INF	ORMATIO	N DIS	CLOSURE	Filing Date	July 18, 2003
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				Art Unit	1643
(Use as many sheets as necessary)				Examiner Name	D. J. Blanchard
Sheet	9	of	10	Attorney Docket Number	BBI-8188

C123	van de Putte, B.A. et al., "Efficacy of the Fully Human anti-TNF Antibody D2E7 in Rheumatoid Arthritis," <i>Arthritis & Rheumatism</i> , Vol. 42(9):S400, No. 1977 (1999)	
C124	Antikörpers D2E7 bei Patienten mit aktiver chronischer Polyarthritis," Z. Rheumatol., Vol. 58(Suppl. 1):1/34, F19 (1999)	V
C125	Van de Putte, L.B.A. et al., "Efficacy and Safety of Adalimumab (D2E7), the First Fully Human Anti-TNF Monoclonal Antibody, in Patients with Rheumatoid Arthritis Who Failed Previous DMARD Therapy: 6-Month Results from a Phase III Study," <i>Ann. Rheum. Dis.</i> , Vol. 61(Suppl. 1):S168 (2002)	
C126	van de Putte, Leo, et al., "Adaliumuab," TNFα-Inhibition in the Treatment of Rheumatoid Arthritis, MD Martin Dunitz, Larry W. Moreland, Ed., pgs. 71-93 (2003)	
C127	van de Putte, L.B.A. et al., "Sustained 5-Year Efficacy of Adalimumab (HUMIRA™) Monotherapy in DMARD-Refractory rheumatoid arthritis (RA)," <i>Arthritis Rheum.,</i> Vol. 48(Suppl. 9):S314 (2003)	
C128	van de Putte, L.B.A. et al., "Efficacy and safety of the fully human anti-tumour necrosis factor α monoclonal antibody adalimumbo (D2E7) in DMARD refractory patients with rheumatoid arthritis: a 12 week, phase II study," <i>Ann. Rheum. Dis.</i> , Vol. 62:1168-1177 (2003)	
C129	Van de Putte, Leo B.A. et al., "A Single Dose Placebo Controlled Phase I Study of the Fully Human Anti-TNF Antibody D2E7 in Patients with Rheumatoid Arthritis," <i>Arthritis Rheum.</i> , Vol. 41:S57 (1998)	
C130	van der Poll, T. et al., "Effect of postponed treatment with an anti-tumour necrosis factor (TNF) F(ab')2 fragment on endotoxin-induced cytokine and neutrophil responses in chimpanzees," Clin. Exp. Immunol., Vol. 100:21-25 (1995)	
C131	van Riel, P.L.C. et al., "Long-Term Treatment with Adalimumab (D2E7) Using Background Methotrexate in Active Rheumatoid Arthritis: Results of a 3 Year Study," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S534 (2002)	
C132	Vaughan, Tristan J. et al., "Human antibodies by design," <i>Nature Biotechnology</i> , Vol. 16:535-539 (1998)	
C133	Velagapudi, R.B. et al., "Pharmacokinetics of Adalimumab (D2E7), a Fully Human Anti-TNF-α Monoclonal Antibody, Following a Single Intravenous Injection in Rheumatoid Arthritis Patients Treated with Methotrexate," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S133 (2002)	
C134	Velagapudi, Raja B. et al., "Effect of Methotrexate (MTX) Coadministration on the Pharmacokinetics (PK) of Adalimumab (HUMIRA™, Abbott) Following a Single Intravenous (iv) Injection," <i>Arthritis Rheum.</i> , Vol. 48(Suppl. 9):S141 (2003)	
C135	Ward, E. Sally et al., "Binding activities of a repertoire of single immunoglobulin variable domains secreted from <i>Escherichia coli</i> ," <i>Nature</i> , Vol. 341:544-546 (1989)	
C136	Weinblatt, M. et al., "The ARMADA Trial: Efficacy and Safety of Adalimumab in Patients with Active RA at 24 Months," <i>Ann. Rheum. Dis.,</i> Vol. 62(Suppl. 1):98 (2003)	
C137		
C138		
C139	Weisman, M.H. et al., "The Importance of Pain and the Impact of Adalimumab on Pain in RA Patients," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):351 (2003)	
C140		

Sub	ostitute for form 1449/PTO			Complete if Known		
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C141	Weisman, Michael H. et al., "Efficacy, Pharmacokinetic, and Safety Assessment of Adalimumab, a Fully Human Anti-Tumor Necrosis Factor-Alpha Monoclonal Antibody, in Adults with Rheumatoid Arthritis Receiving Concomitant Methotrexate: A Pilot Study," Clinical Therapeutics, Vol. 25(6):1700-1721 (2003)	
C142	Wellborne, F. et al., "Adalimumab (D2E7), a Fully Human Anti-TNF-α Monoclonal Antibody, Improved Health-Related Quality of Life in Patients with Active Rheumatoid Arthritis Despite Concomitant Methotrexate Therapy," <i>Arthritis Rheum.</i> , Vol. 46(9 Suppl.):S518 (2002)	
C143	Wells, A.F. et al., "Incidence of Injection-Site Reactions Associated with Adalimumab (D2E7) Give Subcutaneously for at Least 6 Months: A Retrospective Analysis of 4 Phase II/III Clinical Trials," Arthritis Rheum., Vol. 46(9 Suppl.):S171 (2002)	
C144	Wells, A.F. et al., "Injection-site Reactions in Adalimumab Rheumatoid Arthritis (RA) Pivotal Clinical Trials," <i>Ann. Rheum. Dis.</i> , Vol. 62(Suppl. 1):411 (2003)	
C145	Winter, Greg et al., "Making Antibodies by Phage Display Technology," <i>Annu. Rev. Immunol.</i> , Vol. 12:433-455 (1994)	
C146	Winter, Greg et al, "Humanized antibodies," Immunology Today, Vol. 14(6):243-246 (1993)	

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